Louisiana Medicaid
Multiple Sclerosis Agents

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for preferred and non-preferred multiple sclerosis agents.

Additional Point-of-Sale edits may apply.

*These agents may have **Black Box Warnings** and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety Regulations. Please refer to individual prescribing information for details.*

Approval Criteria for Specific Diagnoses

Multiple Sclerosis

- The recipient has a diagnosis of multiple sclerosis; **AND**
- For glatiramer acetate 20mg/ml (generic for Copaxone®) – there has been a treatment failure or intolerable side effect with or contraindication to brand Copaxone® 20mg/ml; **OR**
- For dimethyl fumarate capsules or dimethyl fumarate capsules starter pack (generic for Tecfidera®) – there has been a treatment failure or intolerable side effect with or contraindication to brand Tecfidera®; **AND**
- For cladribine (Mavenclad®), diroximel fumarate (Vumerity®), monomethyl fumarate (Bafiertam®), ofatumumab (Kesimpta®), ozanimod (Zeposia®), or ponesimod (Ponvory®), the recipient is 18 years of age or older on the date of the request; **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a neurologist; **AND**
- **ONE** of the following applies:
    - The request is for a preferred medication; **OR**
    - The request is for cladribine (Mavenclad®), and **ONE** of the following applies:
        - The recipient has had a *treatment failure* with at least **TWO** multiple sclerosis agents (at least **ONE** must be preferred); **OR**
        - The recipient has had an *intolerable side effect* with at least **TWO** multiple sclerosis agents (at least **ONE** must be preferred); **OR**
        - The recipient has *documented contraindication(s)* to **ALL** multiple sclerosis agents that are appropriate to use for the condition being treated; **OR**
        - There are *no multiple sclerosis agents that are appropriate for the condition* being treated; **OR**
    - The request is for any other non-preferred medication [**EXCEPT** cladribine (Mavenclad®)]; **AND**
        - **ONE** of the following applies:
            - There is no preferred product that is the exact same chemical entity, formulation, strength, etc.; **OR**

- The following is true and is **stated on the request** – The recipient is unable to use the chemically equivalent preferred product for reasons such as a contraindication or clinically significant adverse effect(s) to an inactive ingredient that it contains; **AND**

- **ONE** of the following applies:
  - The prescriber **states on the request** that the recipient is currently using the medication; **OR**
  - The recipient has had a *treatment failure* with at least one preferred product that is indicated for treatment of multiple sclerosis; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product that is indicated for treatment of multiple sclerosis; **OR**
  - The recipient has a *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
  - There is *no preferred product that is appropriate to use for the condition* being treated; **AND**

- By submitting the authorization request, the prescriber attests to the following:
  - For cladribine (Mavenclad®), the prescriber has advised patients of reproductive potential to use effective contraception during cladribine dosing and for 6 months after the last dose in each treatment course; **AND**
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Crohn's Disease

- The request is for natalizumab (Tysabri®); **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a gastroenterologist; **AND**
- **ONE** of the following applies:
  - The prescriber **states on the request** that the recipient is currently using the medication; **OR**
  - The recipient has had a *treatment failure* with at least one preferred product that is indicated for treatment of Crohn's disease (see Pain Management – Cytokine and CAM Antagonists on PDL); **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product that is indicated for treatment of Crohn's disease (see Pain Management – Cytokine and CAM Antagonists on PDL); **OR**

- The recipient has a *documented contraindication(s)* to all of the preferred products that are indicated for treatment of Crohn's disease (see Pain Management – Cytokine and CAM Antagonists on PDL); **OR**
- There is *no preferred product that is appropriate to use for the condition* being treated (see Pain Management – Cytokine and CAM Antagonists on PDL); **AND**

- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

<u>Ulcerative Colitis</u>

- The request is for ozanimod (Zeposia®); **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a gastroenterologist; **AND**
- **ONE** of the following applies:
  - The prescriber **states on the request** that the recipient is currently using the medication; **OR**
  - The recipient has had a *treatment failure* with at least one preferred product that is indicated for treatment of ulcerative colitis (see Pain Management – Cytokine and CAM Antagonists on PDL); **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product that is indicated for treatment of ulcerative colitis (see Pain Management – Cytokine and CAM Antagonists on PDL); **OR**
  - The recipient has a *documented contraindication(s)* to all the preferred products that are indicated for treatment of ulcerative colitis (see Pain Management – Cytokine and CAM Antagonists on PDL); **OR**
  - There is *no preferred product that is appropriate to use for the condition* being treated (see Pain Management – Cytokine and CAM Antagonists on PDL); **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**

- All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
- The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria for ALL Diagnoses

- The recipient continues to meet all initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy; **AND**
- If the renewal request is for dalfampridine (Ampyra®), the patient's walking has improved with dalfampridine (Ampyra®) therapy, and this is **stated on the request**; **OR**
- If the renewal request is for alemtuzumab (Lemtrada®):
  - It has been at least 12 months since completion of the most recent treatment course; **AND**
  - The duration of treatment for the renewal is 3 consecutive days; **OR**
- If the renewal request is for cladribine (Mavenclad®):
  - At least 43 weeks have passed since the last dose of the second cycle of the first course of cladribine (Mavenclad®) treatment; **AND**
  - At least 2 years have passed since the last dose of the second cycle of the second course of cladribine (Mavenclad®) treatment.

Duration of initial approval: 12 months (or a 5-day treatment course for alemtuzumab (Lemtrada®) or a 40-day treatment course for cladribine (Mavenclad®)

Duration of renewal approval: 12 months (or a 3-day treatment course for alemtuzumab (Lemtrada®) or a 40-day treatment course for cladribine (Mavenclad®)

References

Ampyra (dalfampridine) [package insert]. Ardsley, NY: Acorda Therapeutics, Inc; February 2021. https://ampyra.com/prescribing-information.pdf

Aubagio (teriflunomide) [package insert]. Cambridge, MA: Genzyme Corporation, A Sanofi Company; April 2021. http://products.sanofi.us/Aubagio/aubagio.html

Avonex (interferon beta-1a) [package insert]. Cambridge, MA: Biogen Inc; November 2021. https://www.avonex.com/content/dam/commercial/multiple-sclerosis/avonex/pat/en_us/pdf/Avonex_US_Prescribing_Information.pdf

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Gilenya (fingolimod) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2019. https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/gilenya.pdf

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Mavenclad (cladribine) [package insert]. Rockland, MA: EMD Serono, Inc; April 2019. https://www.emdserono.com/us-en/pi/mavenclad-pi.pdf

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Ocrevus (ocrelizumab) [package insert]. South San Francisco, CA: Genentech, Inc; March 2021. https://www.gene.com/download/pdf/ocrevus_prescribing.pdf

Plegridy (peginterferon beta-1a) [package insert]. Cambridge, MA: Biogen Inc; November 2021. https://www.plegridyhcp.com/content/dam/commercial/multiple-sclerosis/plegridy/hcp/en_us/home/pdf/prescribing-information.pdf

Ponvory (ponesimod) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; March 2021. PONVORY-pi.pdf (janssenlabels.com)

Rebif (interferon beta-1a) [package insert]. Rockland, MA: EMD Serono, Inc; November 2021. https://www.emdserono.com/content/dam/web/corporate/non-images/country-specifics/us/pi/rebif-pi.pdf

Tecfidera (dimethyl fumarate) [package insert]. Cambridge, MA: Biogen Inc; January 2021. Approval [Rx ONLY] (tecfidera.com)

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Vumerity (diroximel fumarate) [package insert]. Cambridge, MA: Biogen Inc.; January 2021. https://www.vumerityhcp.com/content/dam/commercial/vumerity/hcp/en_us/pdf/vumerity-prescribing-information.pdf

Zeposia (ozanimod) [package insert]. Summit, NJ: Celgene Corporation; May 2021. https://packageinserts.bms.com/pi/pi_zeposia.pdf

Revision / Date	**Implementation Date**
Single PDL Implementation	May 2019
Removed medication list, added wording to allow diagnosis of Crohn's for Tysabri® / August 2019	December 2019
Added specific wording for use of Copaxone® 20mg/ml / November 2019	January 2020
Added clinical criteria for Tysabri® / December 2019	December 2019
Combined Mavenclad® and Mayzent® criteria with Multiple Sclerosis criteria, modified formatting, updated references / June 2020	July 2020
Added wording for Vumerity® and incorporated individual criteria into one document / June 2020	August 2020
Added Zeposia®, formatting changes, updated references / October 2020	April 2021
Added Kesimpta®, updated references / February 2021	July 2021
Added wording regarding use of Tecfidera®, formatting changes / April 2021	July 2021
Added Bafiertam® with reference, formatting changes / May 2021	July 2021
Ponvory® policy created / May 2021	October 2021
Updated indication for Zeposia®, updated references / June 2021	January 2022
Added Ponvory®, updated references / November 2021	January 2022